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URGENT FIELD SAFETY NOTICE

Prometra® Programmable Pump System
RECIPIENTS: Health Care Providers using Prometra® Programmer Software 1.06.1 or prior with Prometra® and Prometra® II Programmable Pumps

August 12, 2019

Product Name:	Prometra® Pump
Catalog No.:	Prometra® Programmer - REF 91828 (software versions 1.03, 1.06, 1.06.1) Prometra® Pump - REF 91827 Prometra® II Pump - REF 93827

Dear Distributor,

The purpose of this letter is to advise you of a software anomaly associated with the Prometra® Programmer with Software Versions 1.03, 1.06, 1.06.1. This software anomaly has the ability to unexpectedly shut down the pump if a certain extended programming sequence is used with the pump while in Periodic Flow or Multiple Rates flow mode, leading to abrupt cessation of drug therapy.

In this case, the pump sounds a one-beep alarm, displays “Error Code 115”, and shuts down. This behavior differs from the Instructions for Use, which state the pump will sound three long (1/2 second) beeps every 30 minutes for all critical errors. Patients abruptly deprived of morphine sulfate or baclofen may suffer a significant reduction in pain relief or withdrawal syndrome due to lack of drug therapy.

To date, Flowonix has received zero (0) reported events related to the Error Code 115 issue from the EU or other countries outside of the USA. In the USA, Error Code 115 events have occurred, however these events were caused by a different US-only version of Programmer and software. Flowonix has conducted non-clinical bench-top testing which demonstrates that pumps programmed with the CE-Marked Prometra Programmer (REF 91828) could abruptly stop during specific programming sequences as described below. Flowonix is providing this notification to help clinicians avoid an unexpected pump stop that could lead to cessation of therapy for patients.

Prometra® Programmer Software Versions 1.03, 1.06, or 1.06.1:

> The software anomaly may cause the pump to shut down if a Healthcare Provider programs a lengthy Demand bolus while the pump is set to either a Periodic Flow or Multiple Rates flow mode. In this case, the programmer displays "Error Code 115" and the pump will need to be explanted. However, this pump stop will only occur after the Demand Bolus is complete, which could take up to seventy-two (72) hours. Accordingly, it is likely that such a shut-down would occur after a patient has left the Healthcare Provider’s office and returned home. Patients whose pumps have been programmed with Constant Flow Therapy are not susceptible to errors of this kind.

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Prometra Pump Error Code 115 Alarm:

In the event of any cause of a Prometra pump Error Code 115, the pump sounds a one-beep alarm and then shuts down. This behavior differs from the Instructions for Use, which state the pump will sound three long (1/2 second) beeps every 30 minutes for all critical errors. As it is unlikely that the patient will notice the single beep, there may be a significant delay in the patient becoming aware that the pump has stopped delivering therapy which may in turn delay resumption of drug therapy.

Flowonix is requiring all Flowonix authorized Distributors or Agents to immediately notify Healthcare Providers, in their assigned regions who are using Prometra® Programmers with Software Versions 1.03, 1.06, 1.06.1 to help clinicians avoid an unexpected pump stop that could lead to cessation of therapy for patients. An Urgent Field Safety Notice for Healthcare Providers is attached. See Attachment B. Please inform Customers of this issue by providing them with this letter.

Actions to be Taken by the Healthcare Provider

All Healthcare Providers should take these steps:

1. STOP using the Demand Bolus feature for patients in a Periodic Flow or Multiple Rates flow mode, as this programming sequence has been determined to be a potential cause of a 115 error and pump stoppage.

   In the event that a Demand Bolus is needed, convert the patient to Constant Flow Mode, then program the Demand Bolus as needed (instructions for use PL-81797-04, page 21). Once the bolus is complete, revisit the patient or have them return to your clinic for programming back to their desired Periodic Flow or Multiple Rates flow mode.

2. IDENTIFY and CONTACT all patients who have had a Demand Bolus programmed while in Periodic Flow or Multiple Rates flow mode. These patients are at high risk of a pump shutdown due to Error Code 115. PERFORM a clinical assessment to determine if they have suffered any harm. ADVISE the patient that if they experience withdrawal symptoms at a later time to immediately contact your office (if during business hours) or call 112.

3. SCHEDULE the patient to have their pump reprogrammed as soon as possible, if a Demand Bolus has been programmed while in Periodic or Multiple Rates flow mode. COUNSEL the patient that if they experience withdrawal symptoms or a significant reduction in pain relief, to immediately contact your office (if during business hours) or call 112.

4. Be aware of and inform patients regarding the one-beep pump alarm for an Error Code 115.

5. Review an excerpt of the Prometra Programmer IFU (PL-81797-04) provided with this Field Safety Notice that provides track changes to the instructions, See Attachment A. The Programmer IFU has been updated to include a warning regarding the programming sequence that should be avoided to prevent the risk of pump shutdown. Note: the complete Prometra Programmer IFU (PL-81797-04) is available on the Flowonix website at www.flowonix.com.

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Follow-up Action by Flowonix Medical

Clinician Programmers: We are developing a solution to address all concerns associated with this issue in a new version of the Programmer. This will take some time. In the interim, the key safeguard is to stop using Demand Bolus features while a patient is in a Periodic Flow or Multiple Rates flow mode, as this programming sequence has been determined to be a potential cause of this error.

Serious Risk to Health

Patients whose pumps stop will have their medication abruptly discontinued.

Patients on INFUMORPH may experience withdrawal syndrome. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. (Reference: Infumorph Package Insert REF ID 4027903, Section 9.3, Recent Changes/Updates 12/2016.)

Patients on baclofen who experience abrupt cessation of the therapy may experience sequelae that include high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity that in rare cases progressed to rhabdomyolysis, multiple organ-system failure, and death. (Reference: Gablofen Package, section 5.5 Insert REF ID MKT-GAB-002-01-JUL-2017, Recent Changes/Updates 03/2017)

Other Information

The appropriate Competent Authorities have been notified of this Field Safety Corrective Action.

As per your distribution agreement with Flowonix, each distributor is responsible for planning, conducting and reporting Field Safety Corrective Action or Recalls in accordance with instructions provided by Flowonix.

To comply with this Safety Notification, Flowonix is requiring all Flowonix authorized Distributors or Agents to notify healthcare providers in their assigned regions who are using Prometra® Programmers with Software Versions 1.03, 1.06, 1.06.1. An Urgent Field Safety Notice for Healthcare Providers is attached. Please inform customers of this issue by providing them with this letter. Please document and maintain records of all actions taken in connection with distribution of this Safety Notification. These records may be requested during an audit conducted by Regulatory Authorities.

Please acknowledge receipt of this Urgent Field Safety Notice by emailing the completed attached Response Form; Attachment A.

Should you have concerns or require further clarification, please contact your Flowonix Representative or our Technical Solutions Department (+1 844-229-6729). Thank you for your cooperation.

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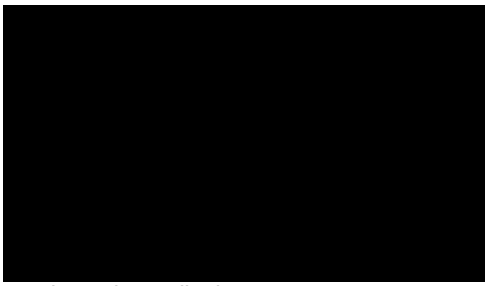
Sincerely,



Flowonix Medical, Inc.

Attachments:
Attachment A: Urgent Field Safety Notice Response Form (PL-71203-01)
Attachment B: Urgent Field Safety Notice for Healthcare Providers (CC FSN2019-035-02)

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URGENT FIELD SAFETY NOTICE RESPONSE FORM
CC FSN2019-035
Prometra® Programmable Infusion Systems

Distributor: _____

Address: _____

City: _____

Country: _____

Acknowledgement:

I have received and read the Flowonix Urgent Field Safety Notice regarding the Clinician Programmer (version 1.03, 1.06, 1.06.1) software anomaly and the one-beep pump alarm for Error Code 115. I will notify Healthcare Providers in my assigned region of these issues by providing them with the Urgent Field Safety Notice.

Signature: _____

Printed Name: _____

Title: _____

Date: _____

EMAIL TO: FieldCorrection@flowonix.com